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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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SCHWEGMAN, LUNDBERG & WOESSNER, P.A. P.O. BOX 2938 MINNEAPOLIS, MN 55402			EXAMINER SMITH, TERRI L	
			ART UNIT 3762	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

ED

Office Action Summary	Application No. 10/730,760	Applicant(s) DYJACH ET AL.	
	Examiner Terri L. Smith	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) 1-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10-30-07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 30 October 2007 has been entered.

Response to Arguments

2. Applicant's arguments filed on 30 October 2007 have been fully considered but they are not persuasive. Applicant's repeated statements that "Applicant is unable to find..." are not persuasive. In response to said statements, the Examiner will cite specific examples in the Kramer et al. U.S. Patent Application Publication 2002/0133198 reference from already cited references in the Office Action mailed on 25 October 2007.

3. Regarding claim 29, Kramer et al., discloses a controller (e.g., FIG. 7, element 728), processing of sensed signals (e.g., paragraph [0069], lines 5-8 and 17-18) and

recording of data to memory (e.g., but not limited to, paragraph [0071], lines 12-16; paragraph [0072], lines 7-8),

data including data indicative of whether the left ventricle cardiac site was paced at the predetermined time interval with respect to the cardiac event at the second cardiac site (e.g., FIGS. 1-7; but not limited to, paragraph [0019], lines 12-22; paragraph [0039], lines 4-18; paragraph [0041], lines 12-17),

a communication circuit (e.g., FIG. 7, element 732) to transmit recorded data to an external device for presentation of data trends useful to assess an efficacy of prescribed CRT (e.g., but not limited to, FIGS. 6–7, elements 642-communication link (radio frequency link), 644-external telemetry device, 648-display screen, 656-printout, 732-receiver/transmitter, 712-transmitter/receiver; paragraph [0063], lines 20–29; paragraph [0065], lines 3–10).

4. With respect to claims 34–41, 49 and 54, the Examiner maintains the position stated in said Office Action in paragraph 6 on Page 3. It is the Examiner's position that the Kramer et al. prior art reference is adapted to record and trend samples of data as set forth in the presently claimed limitations of claims 34–41.

For example, the adapted to record limitations are as shown, e.g., but not limited to, in the data displayed in FIG. 6, elements 648 and 656; FIG. 7, elements 726, 728, 732 and 712 (as described herein above and as described in more detail as cited in said Office Action) and paragraph [0019].

And, the adapted to trend samples of data limitations are also disclosed, e.g., but not limited to, in paragraph [0019], and as shown in the flowchart of FIG. 5 (as described in more detail in said Office Action), where it is readily apparent that sample data is trended because improved settings and attempts to improve left ventricular contractile function are based on various data activity in the heart, which are contemplated by the decision tree structure of the flowchart that uses different algorithms (as described in detail, e.g., in paragraph [0037]) to realize cardiac optimization based on said data activity. Also, algorithms inherently trend data samples because they are constantly comparing, sensing, recording, processing, etc. various

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signals and data, based on various activities in the heart, to generate the best combination of results for achieving the desired optimum treatment.

5. Regarding claims 49 and 52, it is the Examiner's position that the claimed elements, functions, and means for limitations in the system of said claims are readily apparent as cited in all of the limitations of claim 29 as described herein above, and in greater detail of said Office Action, because these independent claims are claiming the same limitations for a system that are being claimed for the apparatus in independent claim 29.

6. In response to Applicant's objection to and traversal of the taking of Official Notice of the missing elements of claims 44 and 57, and the request that the Examiner cite references in support of this position, Examiner points Applicant to paragraph 13 on Page 5 of said Office Action where Examiner did cite references in support of this position.

7. Consequently, Examiner maintains claims 29–60 rejected an anticipated by and unpatentable over Kramer et al., U.S. Patent Application Publication 2002/0133198.

Claim Rejections - 35 USC § 102/103

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 29–43, 45–56, 58, 59 and 60 are rejected under 35 U.S.C. 102(b) as anticipated by Kramer et al., U.S. Patent Application Publication 2002/0133198 or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kramer et al., U.S. Patent Application Publication 2002/0133198.

12. Regarding claims 29, 31–35, 49, 53, 54, 56, 58 and 59 Kramer et al. disclose a plurality of interface channels, a plurality of electrodes, at least one lead (e.g., FIG. 6), a plurality of interface channels adapted to deliver pacing pulses and to receive sensed cardiac signals (e.g., FIGS. 1 and 3, elements 100 and 300, respectively; FIG. 4; paragraphs [0039], [0041] and [0069]);

a memory (e.g., FIG. 7, element 726); a controller (e.g., element 728) adapted to control the prescribed CRT, ...control delivery of pacing pulses, processing of sensed signals, and recording of data to memory, ... (e.g., FIGS. 1–5; paragraphs [0069]–[0073]),

the prescribed CRT including pacing a left ventricle with respect to a cardiac event at a second cardiac site ... (e.g., FIG. 5; paragraphs [0019], [0033], [0051], [0052] and [0070]–[0073]),

a communication circuit (e.g., element 732), an external device for presentation of data trends ... includes recorded data and time associated with recorded data (e.g., FIGS. 5–6 and their corresponding detailed descriptions throughout the written specification; element 644–telemetry device and element 640–medical device programmer; paragraphs [0058]–[0069]);

a programmer (e.g., element 640) including a memory (e.g., element 704); a controller (e.g., 706); a communication circuit (e.g., element 712); and a monitor (e.g., element 648).

13. With respect to claims 30, 50 and 55, Kramer et al. disclose a chronic, ambulatory data (e.g., element 200; paragraphs [0019], [0025], [0028], [0036], [0039] and [0052]).

14. Regarding claims 36–43 and 45–48, Kramer et al. disclose the various claimed limitations of the controller adapted to trend data samples of data indicative of whether the left ventricle cardiac site was paced at the predetermined time interval with respect to the cardiac event at the second cardiac site and the data including a value corresponding to the various claimed limitations as set forth in the present invention as discussed throughout paragraph 4 herein above as well as disclosed in the detailed descriptions of Kramer et al. of the figures cited herein above.

15. With respect to claim 60, Kramer et al. disclose means for detecting a trigger, and means for trending data samples based on a trigger (e.g., FIGS. 1–3 and 5; paragraphs [0021]–[0022] where it is the Examiner's position that the trigger limitation is realized by the information provided by the electrogram that helps select which improved resynchronization parameter

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values are desired. The Examiner's position is consistent with Applicant's written specification on page 11, lines 13–28 that discusses the trigger limitation.).

16. In the alternative, claims 29, 36–41, 49 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kramer et al., U.S. Patent Application 2002/0133198.

17. Kramer et al. disclose the essential features of the claimed invention as described above except not explicitly data trends, time associated with recorded data, and trend samples of data. However, it is well known in the art to include data trends, time associated with recorded data, and trend samples of data to yield the predictable results of optimizing pacing delay between two or more sites within the heart by trending a stream of data to characterize a patient's status and to show worsening and/or improving condition with respect to the paced heart.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Kramer et al. to include data trends, time associated with recorded data, and trend samples of data to yield the predictable results of optimizing pacing delay between two or more sites within the heart by trending a stream of data to characterize a patient's status and to show worsening and/or improving condition with respect to the paced heart.

18. Claims 44 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kramer et al., U.S. Patent Application 2002/0133198.

19. Regarding claim 44, Kramer et al. disclose the essential features of the claimed invention as described above except for data that includes a value corresponding to atrial tachycardia (AT).

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However, it is well known in the art to use data that includes a value corresponding to atrial tachycardia (AT) to yield the predictable result of effectively recognizing a cardiac anomaly in a forecast cardiac event and subsequently select and initiate appropriate cardiac resynchronization therapy.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Kramer et al. to include data that includes a value corresponding to atrial tachycardia (AT) to yield the predictable result of providing appropriate, effective and safe cardiac resynchronization therapy.

20. With respect to claim 57, Kramer et al. disclose the essential features of the claimed invention as described above except for a table of trended data. However, it is well known in the art to use a table of trended data to yield the predictable results of clearly and accurately displaying patient information for ease of interpretation and diagnosis by a medical care provider.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Kramer et al. to include a table of trended data to yield the predictable results of rendering easy-to-read patient information for accurate diagnosis by a medical care provider.

Conclusion

21. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. Ganion et al., U.S. Patent 7,184,833 and Stahmann et al., U.S. Patent Application Publication 2002/0082660 disclose a value corresponding to atrial tachycardia (AT). Marcus et al., U.S. Patent 6,978,184 discloses a table of trended data. Kramer et al., U.S. Patent

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Application Publication 2003/0060851 teaches data trends, time associated with recorded data, and trend samples of data.

22. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Terri L. Smith whose telephone number is (571) 272-7146. The Examiner can normally be reached on Monday - Friday between 7:30 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



TLS

November 17, 2007

17 November 2007

GEORGE R. EVANISKO
PRIMARY EXAMINER

11/21/07